UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,871	04/13/2004	Robert J. Deleys	BJS-2551-141	3673

23117 7590 03/28/2011

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
03/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,871	DELEYS ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55,59,60,62,68-76 and 81-93* is/are pending in the application.

4a) Of the above claim(s) *74-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55, 59, 60, 62, 68-73 and 81-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/18/04 and 4/13/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/920,286.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. Claims 55, 59, 60, 62, 68-73 and 81-89 are examined on the merits. Claims 74-76 remain withdrawn from consideration as they are drawn to non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicants' arguments filed 9/23/2010 have been fully considered but they are not persuasive. See responses below.

Claim Rejections - 35 USC § 102

(New Rejection) Claims 55, 59, 60, 62, 68-73 and 81-89 are rejected under 35 U.S.C. 102(e) as anticipated by Houghton et al. (US 6,861,212) [a divisional of 08/307,273, which is a divisional of 08/306,472, which is a continuation of 08/103,961, which is now US Patent 5,350,671-previously cited in Office action mailed on 5/21/2009].

The claimed invention is drawn to a combination of three distinct peptides of HCV each consisting of a specific amino acid sequence. The first peptide comprises at least 5 amino acids from SEQ ID NOs: 1-8 or from at least 5 amino acids of corresponding amino acid positions 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 or 73-92 of the HCV polyprotein of SEQ ID NO: 23. The second peptide comprises at least 5 amino acids from SEQ ID NOs: 9-15 or from at least 5 amino acids of corresponding

amino acid positions 1688-1707, 1694-1713, 1706-1725, 1712-1731, 1718-1737, 1724-1743 or 1730-1749 of the HCV polyprotein of SEQ ID NO: 23. The third peptide comprises at least 5 amino acids from SEQ ID NOs: 16-20 or at least 5 amino acids of corresponding amino acid positions 2263-2282, 2275-2294, 2287-2306, 2299-2318 or 2311-2330 of the HCV polyprotein of SEQ ID NO: 23. In addition, the combination also requires that at least one additional molecule be included. The at least one additional molecule is selected from SEQ ID NO:s 1-20, or at least 5 amino acids of a region corresponding to amino acids: 7 to 26, 13 to 32, 37 to 56, 49 to 68, 61 to 80, 73 to 92, 1688-1707, 1694 to 1713, 1706 to 1725, 1712 to 1731, 1718 to 1737, 1724 to 1743, 1730 to 1749, 2287 to 2306, 2299 to 2318, 2311 to 2330 [all of SEQ ID NO: 23]; or at least 5 amino acids of SEQ ID NO: 2, 4, 6, 9-20; or at least 5, 6, 8, 12 or 20 amino acids of a HCV polyprotein of an isolate corresponding to a region represented by amino acids 61 to 80, 37 to 56, or 73 to 92 of SEQ ID NO: 23. The peptides are produced by either recombinant expression or by chemical synthesis, and one or more of the peptides comprises a fusion protein, which can be synthetic. The combination of peptides is also part of a kit for detecting HCV infection in a human body component by screening for reactive antibodies for the peptides of the claimed invention that are coating an immunoassay plate. Therefore, given the broadest reasonable interpretation, the claimed invention is a peptide combination of at least 4 HCV polyprotein fragments that are different from each other in which at least 5 amino acids of each fragment must either be identical to any 5 amino acid residues from 4 sequences of SEQ ID NO:s 1-20 or any 5 amino acid residues of any HCV polyprotein (which includes non-full length polyproteins).

Houghton et al. teach the development of a peptide library of HCV. The peptides of the library could be as short as 5 amino acids. These peptides can be employed in an assay for detecting HCV specific antibodies in biological fluids and can be a fusion protein between the HCV peptide and Super Oxide Dismutase (SOD). One example of such an assay is an ELISA, in which the peptides can be added to the wells of a plate and the reactive antibodies can be detected. Houghton et al. further teach that "An antigenic region of a polypeptide is generally relatively small--typically 8 to 10 amino acids or less in length. Fragments of as few as 5 amino acids may characterize an antigenic region. These segments may correspond to regions of HCV antigen...polypeptides comprising truncated HCV amino acid sequences encoding at least one viral epitope are useful immunological reagents. For example, polypeptides comprising such truncated sequences can be used as reagents in an immunoassay. These polypeptides also are candidate subunit antigens in compositions for antiserum production or vaccines. While these truncated sequences can be produced by various known treatments of native viral protein, it is generally preferred to make synthetic or recombinant polypeptides comprising an HCV sequence. Polypeptides comprising these truncated HCV sequences can be made up entirely of HCV sequences (one or more epitopes, either contiguous or noncontiguous), or HCV sequences and heterologous sequences in a fusion protein. Useful heterologous sequences include sequences that provide for secretion from a recombinant host, enhance the immunological reactivity of the HCV epitope(s), or facilitate the coupling of the polypeptide to an immunoassay support or a vaccine carrier...The size of polypeptides comprising the truncated HCV sequences can vary widely, the minimum size being a

sequence of sufficient size to provide an HCV epitope, while the maximum size is not critical. For convenience, the maximum size usually is not substantially greater than that required to provide the desired HCV epitopes and function(s) of the heterologous sequence, if any. Typically, the truncated HCV amino acid sequence will range from about 5 to about 100 amino acids in length. More typically, however, the HCV sequence will be a maximum of about 50 amino acids in length, preferably a maximum of about 30 amino acids. It is usually desirable to select HCV sequences of at least about 10, 12 or 15 amino acids, up to a maximum of about 20 or 25 amino acids." See column 27, lines 3-6 and 59-68 and column 28, lines 1-10 and lines 15-29. Some suggested amino acid regions that can be tested are provided below

AA-AA of Houghton et al.	Claimed Amino acid positions
AA1-AA25	1-20, 7-26
AA5-AA20	8-18
AA1-AA50	13-32
AA1-AA84	37-56
AA45-AA65	49-68
AA65-AA75	61-80
AA80-AA92	73-92
AA1690-AA1720	1688-1707, 1694-1713, 1706-1725
AA1694-AA1735	1712-1731, 1718-1737
AA1720-AA1745	1724-1743, 1730-1749
AA2265-AA2280	2263-2282
AA2250-AA2330	2275-2294
AA2290-AA2310	2287-2306, 2299-2318
AA2310-AA2330	2311-2330

In addition, the patented invention of Houghton et al. is drawn a method of selecting biological samples form a human that contain antibodies that can form an antigen-

antibody complex with an amino acid sequence of at least 10 contiguous amino acids encoded by a hepatitis C virus genome. The "…selected samples comprise one or more contiguous amino acid sequences from the following group: AA1-Aa50; AA1-AA84; AA9-AA177; AA1-AA120; AA35-AA45; AA50-AA100; AA40-AA90; AA65-AA75; AA80-AA90;…AA1685-AA1770; AA1689-AA1805; AA1690-AA1720; AA1694-AA1735; AA1720-AA1745;…AA2200-AA2345; AAAA2250-AA2330; AA2265-AA2280; AA2280-AA2290; AA2887-AA2385; AA2300-AA3250;…" See claims 1 and 65.

Response to arguments of applicant's response of 11/23/2009:

Applicants argue that the while Houghton et al. do list numerous peptides that overlap with the amino acid sequences presently claimed, they do not establish that each of these peptides can form an epitope or be immunogenic. Therefore, without knowing whether or not if these peptides can form an epitope, such peptides couldn't be used in an immunoassay for detecting the presence of HCV antibodies (i.e., ELISAs) or be used in the induction of such antibodies. Furthermore, Houghton et al. do not establish that a combination of these peptides with confirmed epitope formation can be used based on peptides from the Core, NS4 and NS5 proteins of HCV, they do not anticipate the claimed invention. Applicants also state that it is these combinations of their proteins that improve the detection and confirmation of HCV infections in a subject.

In response, Houghton et al. teach that truncated HCV polyproteins used in immunoassays can be relied upon for detecting antibody-antigen interactions. The patented invention of Houghton et al. is drawn to such a method that involves several examples of peptides with at least 5 amino acids in common with those of parts (a), (b),

(c) and the additional peptide requirement of the instant invention (see claim 65). Since the patented invention is drawn to a method that relies on epitope recognition on the HCV peptides, Houghton et al. do establish that their amino acid sequences which include the breadth of applicant's peptide combinations do present the necessary epitopes for carrying out an immunoassay. Furthermore, while applicants argue that their combination of Core, NS4 and NS5 peptides results in an improved multispecific immunoassay for detecting HCV infections, such an improvement is not associated with the claimed breadth of a protein combination based on at least 5 amino acids in common with those that are claimed, rather, with the full peptide fragment of SEQ ID NO:s 9-20 (fragments of the NS4 and NS5 proteins) as presented in the response of November 2, 2007.

In addition and as stated in the Office action mailed on 2/5/2008 (see page 5), "... For example, the inventors state in these comparison tests that the Houghton et al. peptides "react in a very similar way with the HCV positive samples tested and in comparison with peptide VIII" (see page 8 of 11/2/07 response). Furthermore, applicants state on page 14 of the same response that peptide XIII of the instant invention "did not show any advantages in an ELISA format over peptide 1720-1745", a Houghton et al. peptide..."

Based on these teachings of Houghton et al. and the method of the patented invention of '212 and in view of the breadth of the instant invention permitting that at least 5 amino acids of each claimed amino region of Core, NS4, NS5 and an additional peptide from one of these proteins of HCV be combined into a combination for the basis of an immunoassay, the instant invention is rendered anticipated by Houghton et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648